Centre universitaire de santé McGill
McGill University Health Centre

TECHNOLOGY ASSESSMENT UNIT

POLICY COMMITTEE

GUIDELINES

16 January 2015

Suggested citation:

MUHC TAU Members. Technology Assessment Unit Policy Committee Guidelines, version 1.0. Montreal (Canada): Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC); 16 January 2015.

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1. BACKGROUND

The purpose of the Technology Assessment Unit (TAU) is to advise the McGill University Health Centre (MUHC) in difficult resource allocation decisions, using an approach based on sound, scientific technology assessments, and a transparent, fair decision-making process. TAU has two distinct functions. The first is the preparation of Health Technology Assessment (HTA) reports reflecting the efficacy, effectiveness, risks, and costs of technologies under review. The second is the development (in most reports) of recommendations on the policies the hospital should adopt in the light of these data. The former is the responsibility of the professional staff while development of policy recommendations is the responsibility of the Policy Committee. It should be noted that the TAU policy committee is Advisory in nature. Responsibility for accepting and implementing the recommendations lies with the MUHC Administrator and Chief of Department identified in the report.

2. OBJECTIVE

The following document describes the composition and mode of function of the TAU Policy Committee and lists the principal criteria used for evaluating the evidence in HTA reports and for developing recommendations based on them.

3. TERMS OF REFERENCE

- **Composition of the Policy Committee.**

  In addition to the Chairperson, the Policy Committee consists of the following members:

  - The Director of the TAU professional staff serves ex-officio.
  - Five *permanent* members are nominated by the following five organisations: The Patients committee, The Council of Nurses, The Multidisciplinary committee, The Council of Physicians and Dentists, and the Hospital Administration

- Up to four *permanent* members are appointed by TAU for their special expertise in subjects such as Clinical Epidemiology, Pharmacy, Quality Management, Medical Ethics, Health Economics and Biomedical Engineering.
- Past chair persons of the Policy Committee may be invited to serve as a permanent members.
- Up to two *temporary* members may be appointed for specific studies for their expertise in disciplines such as Ethics, Economics etc.
- At least 1 and up to 2 *temporary* members are appointed from the department or discipline most affected by the technology in question. These members assist the TAU throughout the preparation of a report. Final recommendations are not normally approved in their absence.

- **Conditions of membership**

Membership in the committee is honorary. Permanent members of the Committee are appointed for a period of 3 years with possible extension for a further 3 years by mutual agreement. The Chair of the Policy Committee is nominated by the Director General of the MUHC for a five-year term, renewable.

- **Policy Committee Meetings**

There are normally 4 quarterly meetings each year with ad hoc meetings when required. Dates/times of meetings are fixed several months in advance to facilitate attendance. To provide ample discussion time at meetings, pre-final drafts of HTA reports are circulated to Committee members at least 3 weeks prior to the meeting at which they will be discussed, and, members submit their comments and corrections to the TAU for incorporation in the final document before the meeting. An agenda is circulated in the weeks prior to each meeting listing the reports to be discussed and any other relevant issues. Meetings are presided over by the Chair of the TAU Policy Committee or in his or her absence

by a named delegate. Each report is presented briefly by a member of the TAU professional staff involved in its preparation. The topic is then opened for discussion. The committee discusses evidence and opinions and seeks to reach a consensus. Statements of committee members made at meetings shall be relevant to the matter under discussion and the decision of the chair on questions of order, relevancy and interpretation (including conflicts of interest) shall be clearly documented in the minutes and will be final. The draft minutes of the committee proceedings shall be drawn up and submitted to the next meeting for approval.

- **Meeting Attendance**

  Since the Committee is responsible for major policy recommendations involving the services and budget of the MUHC, regular attendance of members is essential and members who are frequently unable to attend meetings are expected to request replacement. Members are required to be present at a minimum 75% of the meetings per year. In the event they cannot attend they may send a delegate who is pre-approved by the Chair of the committee. The delegate will be required to read the reports being discussed and participate in the discussion and policy development. In the event a member is unable to attend a they may in exceptional circumstances request permission from the Chair to participate in the meeting via such means as video conference.

- **Quorum**

  No decisions should be taken in the absence of a quorum, i.e. 60% of the permanent members.

- **Code of ethics**

Members of the committee shall be bound by the principles of: collegiality, integrity, objectivity, accountability, openness and honesty. As members of the MUHC community, committee members are bound by the MUHC code of ethics.

- **Confidentiality**

Meetings are open to all interested parties. Individuals who are not on the TAU Policy Committee or TAU professionals who wish to attend must request invitation.

- **Voting**

All members, including temporary members, have the right to vote. Final decisions of the Committee are usually arrived at by consensus. When this is not possible decisions are approved by majority vote of all participating members (absentee voting is not permitted). Dissenting votes are minuted (the name of the dissenting voter(s) with a brief description of the reasons for dissent), and included in the final report.

- **Levels of Recommendations**

Decisions to approve/reject a technology usually conform to one of the following categories (Examples of reports that resulted in each level of recommendation is given in the Appendix A.

Approval of a technology for use within the MUHC is given when there is agreement that the level of health benefit, risk, and costs are appropriate, and that the evidence for these modalities is of adequate quality .Approval may be unconditional, or it may be accompanied by limits and conditions (e.g. the presence of specific clinical indicators, prior use of other measures etc.)

Conditional approval may be given when there is a high probability that the health technology under review is effective, safe, and affordable, but the evidence is not yet sufficient in quality or quantity to justify unconditional approval. When this occurs

approval may be given for *temporary, limited* use of the technology, under *strictly defined conditions* (e.g, number of interventions restricted, review of outcomes or procedures at specific intervals, a field evaluation, or a complete review of the evidence, may be recommended).

Rejection of a technology is recommended when the conditions for approval and conditional approval are not met. Rejection of a technology may be unconditional (it should not be used in the MUHC under any circumstances), or conditional (it may be used in the context of a formal research study).

- **Dissemination**

Once an HTA report including its recommendations has been approved by the TAU Policy Committee the completed HTA report is submitted to the hospital's decision-making authority and also widely distributed and put on the web.

4. ISSUES TO BE CONSIDERED WHEN FRAMING TAU POLICY RECOMMENDATIONS

When developing policy recommendations, in addition to objective scientific evidence, consideration must also be given to subjective criteria, e.g. ethics and institutional values, in developing a policy recommendation about a health technology. The mission, vision and values of the MUHC (http://muhc.ca/homepage/page/our-vision-mission-and-values) are duplicated in the Appendix B for reference.

1. Criteria considered by the Policy Committee in the evaluative process

The committee evaluates each technology according to the following criteria: i) context-free scientific evidence of net clinical benefit to the patient, including its efficacy, effectiveness, safety, number of cases admitted to the MUHC annually and need, ii)) cost-effectiveness from the point of view of the MUHC, iv) feasibility of implementation v) Budget impact, and opportunity cost from the point of view of the MUHC.

2. Evaluation of quality of scientific evidence

Evidence from high-quality randomized controlled trials is considered the highest quality and preferable to evidence from non-randomized studies. The TAU frequently evaluates technologies for which evidence from randomized controlled trials is not available. This may be because the technology is still early in its development or because a study employing a randomized study design is not feasible. In the former case approval is not given and it is recommended that the issue be reviewed at some future date, usually specified. In the latter case it is necessary to make a decision on the available, admittedly incomplete evidence. The decision will then be influenced by such factors as the effect size of clinical benefit, the adequacy of the evidence concerning safety, and the size of budget impact and opportunity cost. At the same time, the possible negative consequences of approving a technology that is potentially harmful or ineffective, even if inexpensive, should be weighed.

3. Interpretation of cost analyses and cost-effectiveness analyses

The cost of a technology and its net budget impact, are presented in all HTA reports, and formal cost utility analysis is sometimes carried out in order to facilitate comparison with different technologies. The MUHC does not use any pre-defined cost-effectiveness ratio or other criteria to limit acquisition of technologies.

4. Consideration of opportunity cost

The opportunity cost of a choice is defined as the value of the best alternative forgone (ref, Wikipedia). Under Quebec laws, the MUHC is required to function without incurring a budget deficit. Thus the acquisition of a new technology at a net cost will mean a reduction of some other health services elsewhere in the hospital. It is impossible to draw a direct connection between a particular new technology and the services that will have to be reduced in order to acquire it. Accordingly, to remind decision makers that the decision in question involves opportunity costs.TAU reports frequently estimate the potential opportunity cost of a new technology in terms of the number of acute hospital beds that would need to be closed down annually in order to acquire it. Though there are no general guidelines on how to interpret this

information, it does help frame the overall impact of recommendations in terms that easily understandable for both the scientific and lay communities.

5. Consideration of increased efficiency

Sometimes a new technology may result in a decrease in usage of hospital resources (e.g. operating room usage, bed-days). Since, under operating conditions any such decrease in use of resources will result in increased use of resources elsewhere, this s cannot be interpreted as a ‘savings’. Rather it is viewed as an increase in efficiency because the freed resources will inevitably be used to serve more patients than was previously possible, without increase in cost. Although, there is no way to turn this into a cost advantage for the MUHC, the improvement of efficiency is valuable and should not be overlooked by decision-makers.

5. APPENDIX A

Examples of TAU reports resulting in different levels of recommendation

1. **Approval: Subglottic secretion drainage endotracheal tubes for prevention of ventilator-associated pneumonia (VAP)**

Efficacy: Evidence of efficacy obtained from 14 randomized controlled trials (RCTs). The average reduction in risk of VAP based on all studies was 47% (95% credible interval 36%, 53%).

Safety: No particular concerns.

Cost: Application of this technology to an estimated 500 patients per year would result in:

- Prevention of 20 cases of VAP per year.
- An estimated reduction in ICU occupancy due to VAP of 86 bed days (95% credible interval 65days, 103 days), with an equivalent increase in the number of other patients treated.
- The budget impact of this intervention (the cost of the necessary equipment) would be $9,250.

Interpretation: Due to the non-blinded nature of the trials, the possibility cannot be excluded that the estimated benefit might be the result of bias or confounding due to the occurrence of other therapeutically effective co-interventions. Thus, further more methodically rigourous trials are very desirable, In spite of this, , the available evidence of benefit is sufficiently convincing to serve as the basis for MUHC policy in the case of this relatively low-cost, apparently harmless intervention

2. **Conditional Approval: Trans-aortic valve insertion (TAVI) for patients who are inoperable (This technology received conditional approval in a first report and was subsequently approved for routine use in an update)**

Efficacy:

- First report: Evidence was gathered from 16 case series and one substantial multicentre registry describing the procedure in a total of 1,262 subjects. Review of this evidence indicates the procedure can be carried out with an anticipated 30 day mortality of 8-10%, and a subsequent mortality of approximately 24% and 35%, at one and two years respectively. Survivors can be expected to experience substantial physiological and symptomatic improvement.

- Update: We found marked functional improvement and survival rates of the order of 95%, 69.3%, and 56.7% at 30 days and one and two years respectively, based on data from the PARTNER B trial

Safety:

- First report: Serious but mostly manageable complications can be expected in 25-30% of procedures.
- Update: At 30 days, the rate of major stroke was 5.0% for TAVI versus 1.1% for medical management, while the rate of major vascular complications was 11.0% for TAVI versus 3.2% for medical management.

Cost:

- First report: The average net cost per patient was estimated to be $24,024. Assuming a turnover of 30 per year the anticipated budget impact would be $720,719. There are insufficient data on which to estimate cost effectiveness.
- Update: Cost of TAVI is $29,755 per patient. Comparison of costs in TAVI versus medical management in inoperable patients is less certain, since it is difficult to estimate the cost of medical management precisely.

MUHC experience:

- First report: 12 patients had undergone the procedure in the MUHC.
- Update: 99 patients had undergone TAVI at the MUHC. Mortality at 30 days, 1 year, and risk of complications were similar to outcomes reported in the literature.

Interpretation:

- First report: This is an effective technology that should continue to be funded by the MUHC. Since this is a relatively new procedure, and one in which both the selection of patients and its execution are crucial for success, the Cardiovascular Division should maintain a registry, including follow-up, of all cases. The register should be examined by the MUHC in approximately one year at which time the decision to continue funding should be reviewed .
- Update: For inoperable patients with reduced life expectancy due to severe symptomatic aortic stenosis, if age and comorbidity are such that a continuing life of adequate quality can be anticipated, valve replacement by the TAVI procedure should now be considered standard of care. The practice of sharing responsibility for patient selection by a multidisciplinary team, of recording that this has been done, and of recording all relevant clinical material in a registry, should continue.

3. Rejection (not recommended for use in MUHC): Probiotics for prevention of *C. difficile* diarrhea

Efficacy: Evidence was available from 7 RCTs. The average benefit of probiotics across these studies was estimated to be an 83% reduction in *C. difficile* diarrhea. Though the uncertainty interval around the average effect was statistically significant ranging from (58% to 96%), the interval around the expected effect in a future trial was much wider including the possibility of no effect or a harmful effect (-49%, 96%).

Safety: In general the safety profile was benign.

Cost: Not estimated in the report. At the policy committee meeting it was discussed that though the cost of the probiotic itself is believed to be relatively inexpensive, there may be additional unforeseen costs such as the cost of nursing time required to allocate these drugs to all patients.

Interpretation: Although there is suggestive evidence that probiotics based on Lactobacillus may be effective in the prevention of CDAD, the evidence is not strong enough to recommend them for routine use.

4. Rejection (recommended for use with research support only): Renal Denervation for treatment of resistant hypertension

Efficacy: Evidence was drawn from a recent systematic review of 19 studies comprising 683 patients. The lone RCT and largest cohort study were reviewed further. The RCT concluded that a significant reduction in BP can be achieved with catheter based renal denervation in patients with resistant hypertension. However, there were a number of concerns about the validity of the evidence due to the non-blinded study design and the short-term follow-up for only 6 months. Though the cohort study reported optimistic results till 2 year follow-up, it was based on only 12% of patients initially recruited.

Safety: No serious complications related to the device or procedure were reported in the literature.

Cost: The total cost of each procedure is $4,085. Assuming 20 renal denervation procedures are carried out per year at an anticipated cost of $4,085 per procedure, the budget impact to the MUHC would be $81,700.

Interpretation: There is a need for further research to verify the expected benefits of this procedure, to establish that they are long-lasting, and to better estimate the rate and severity of complications. This technology should be only applied in the context of a formal research study. Renal denervation procedures should be limited to a maximum of 20 per year and subsidized by the manufacturer as indicated above. The question of permanent approval be reconsidered at a maximum of two years after the first procedure is completed.

6. APPENDIX B

Vision, Mission and Values of the McGill University Health Centre

Vision As one of the world's foremost academic health centres, the MUHC will assure exceptional and integrated patient-centric care, research, teaching and technology assessment.

Mission The MUHC is the adult and pediatric academic health centre that is partnered with McGill University. Our mission is to:

5. Offer our pediatric and adult patients as well as their families compassionate exemplary care, with a specific commitment to treating complex cases;
6. Extend the limits of health knowledge through research and integrate this new knowledge to our clinical and teaching practices;
7. Provide outstanding health science education to healthcare providers, administrators and the community; and
8. Assess the introduction, acquisition and use of health technologies and the methods of organizing and providing services.

Values

- Service: Patients and their families are our raison d'être. We provide compassionate multidisciplinary care of the highest quality and safety throughout a person's lifespan. We relate to patients and their families in a transparent way that respects their dignity as well as their cultural and linguistic needs.
- Innovation: We foster a culture of inquiry and innovation. We make evidence-informed decisions. We strive continuously to improve our efficiency and efficacy.
- Leadership: We develop, use and disseminate continuously new knowledge and expertise that can benefit patients locally and globally. We exercise our influence with a view to improving the functioning of the healthcare system at the local, regional, national and international levels.
- Partnership: We work in collaboration with our employees, our ambassadors, as well as our health network partners to ensure comprehensive integrated services across the continuum of care for the population we serve.